Appendix D: Vaccine Safety

Appendix D

Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national post-licensure vaccine safety surveillance program co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS serves as an early warning system to detect possible safety issues with U.S. vaccines by collecting information about adverse events (possible side effects or health problems) that occur after vaccination. A report to VAERS does not indicate that a vaccine caused an adverse event, only that the adverse event occurred sometime after vaccination.

Who can report?

Anyone can submit a report to VAERS — healthcare professionals, vaccine manufacturers, and the general public. VAERS welcomes all reports, regardless of seriousness, and regardless of how likely the vaccine may have been to have caused the adverse event.

What should be reported?

Healthcare providers are **required by law** to report:

- Any adverse event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine
- Any adverse event listed in the Reportable Events Table that occurs within the specified time period after the vaccination.

Healthcare providers are strongly **encouraged** to report:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
- Vaccine administration errors

A copy of the Reportable Events Table can be found on the following page, or at https://vaers.hhs.gov/resources/infoproviders.html

Note: COVID-19 vaccines under an Emergency Use Authorization have additional VAERS reporting requirements. See https://vaers.hhs.gov/faq.html.

How do I report?

There are two ways to report to VAERS:

Option 1: Online (preferred). Submit a VAERS report using the online reporting tool at https://vaers.hhs.gov/esub/index.jsp

Before you begin, review the Checklist for Completing the VAERS form at https://vaers.hhs.gov/reportevent.html. Information submitted using the online reporting tool is transmitted securely to VAERS.

Option 2: Writeable PDF Form. Download the writable PDF form (located at https://vaers.hhs.gov/uploadFile/index.jsp) to your computer, complete it, and then return to the VAERS website to upload the completed form. It is important that you use a desktop or laptop computer on which you can securely save a document that contains protected health information, personal identifiers or other sensitive personal or patient information. When you upload the form, the information is transmitted securely to VAERS.

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What are the strengths and limitations of VAERS data?

When evaluating VAERS data, it is important to understand the strengths and limitations. VAERS data contain both coincidental events and those truly caused by vaccines.

Strengths:

- VAERS collects national data from all U.S. states and territories.
- VAERS accepts reports from anyone.
- The VAERS form collects information about the vaccine, the person vaccinated, and the adverse event.
- Data are publicly available.
- VAERS can be used as an early warning system to identify rare adverse events.
- It is possible to follow-up with patients to obtain health records, when necessary.

Limitations

- It is generally not possible to find out from VAERS data if a vaccine caused the adverse events.
- Reports submitted to VAERS often lack details and sometimes contain errors.
- Serious adverse events are more likely to be reported than mild side effects.
- Rate of reports may increase in response to media attention and increase public awareness.
- It is not possible to use VAERS data to calculate how often an adverse event occurs in a population.

Where can I find more information?

If you need further assistance with reporting to VAERS, please email info@vaers.org or call 1-800-822-7967. Operators are on duty from 9:00 a.m. to 5:00 p.m., Eastern Time, Monday through Friday.

For more information, visit the VAERS website at https://vaers.hhs.gov/

VAERS Table of Reportable Events Following Vaccination*

Vaccine/Toxoid	Event and Interval ** from Vaccination
Tetanus in any combination: DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Brachial neuritis (28 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pertussis in any combination: DTaP, DTP, DTP-Hib, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (7 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles, mumps and rubella in any combination: MMR, MMRV, MM	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (15 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rubella in any combination: MMR, MMRV	A. Chronic arthritis (42 days) B. Any acute complications or sequelae (including death) of above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles in any combination: MMR, MMRV, MM	A. Thrombocytopenic purpura (7-30 days) B. Vaccine-strain measles viral infection in an immunodeficient recipient • Vaccine-strain virus identified (interval – not applicable) • If strain determination is not done or if laboratory testing is inconclusive (12 months) C. Any acute complications or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Oral Polio (OPV)	A. Paralytic polio • in a non-immunodeficient recipient (30 days) • in an immunodeficient recipient (6 months) • in a vaccine-associated community case (interval - not applicable) B. Vaccine-strain polio viral infection • in a non-immunodeficient recipient (30 days) • in an immunodeficient recipient (6 months) • in a vaccine-associated community case (interval - not applicable) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

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Vaccine/Toxoid	Event and Interval ** from Vaccination
Inactivated Polio in any combination: IPV, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hepatitis B in any combination: HepB, HepA-HepB, DTaP-HepB-IPV, Hib-HepB	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complications or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
***Haemophilus influenzae* type b in any combination (conjugate): Hib, Hib-HepB, DTaP-IPV/Hib, Hib-MenCY**	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Varicella in any combination: VAR, MMRV	A. Anaphylaxis or anaphylactic shock (7 days) B. Disseminated varicella vaccine-strain viral disease • Vaccine-strain virus identified (time interval unlimited) • If strain determination is not done or if laboratory testing is inconclusive (42 days) C. Varicella vaccine-strain viral reactivation (time interval unlimited) D. Shoulder Injury Related to Vaccine Administration (7 days) E. Vasovagal syncope (7 days) F. Any acute complication or sequelae (including death) of above events (interval - not applicable) G. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rotavirus (monovalent or pentavalent) RV1, RV5	A. Intussusception (21 days) B. Any acute complication or sequelae (including death) of above events (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pneumococcal conjugate (7-valent or 13-valent) PCV7, PCV13	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hepatitis A in any combination: HepA, HepA-HepB	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Seasonal influenza (trivalent inactivated influenza, quadrivalent inactivated influenza, live attenuated influenza): IIV, IIV3, IIV4, RIV3, ccIIV3, LAIV4	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Guillain-Barré Syndrome (42 days) E. Any acute complication or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

Vaccine/Toxoid	Event and Interval ** from Vaccination
Meningococcal: MCV4, MPSV4, Hib-MenCY, MenACWY, MenB	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Human Papillomavirus (quadrivalent, bivalent, or 9 valent): 9vHPV, 4vHPV, 2vHPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children.	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

* Effective date: March 21, 2017. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine.

Note that the RET differs from the Vaccine Injury Table (VIT) regarding timeframes of adverse events. Timeframes listed on the RET reflect what is required for reporting, but not what is required for compensation. To view timeframes for compensation, please see the VIT at https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf.

**Represents the onset interval between vaccination and the adverse event. For a detailed explanation of terms, see the Vaccine Injury Table at https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf.

YOU CALL THE SHOTS

Vaccine Administration: Preventing Vaccine Administration Errors

A vaccine administration error is any preventable event that may cause or lead to inappropriate medication use or patient harm.[1] Vaccine administration errors can have many consequences, including inadequate immunological protection, possible injury to the patient, cost, inconvenience, and reduced confidence in the health care delivery system. Take preventive actions to avoid vaccine administration errors and establish an environment that values reporting and investigating errors as part of risk management and quality improvement.

Vaccine administration errors may be due to causes such as:

- Insufficient staff training
- Distraction
- Changes in recommendations
- Lack of standardized protocols
- Patient misidentification
- Using nonstandard or error-prone abbreviations
- Easily misidentified products (e.g. DTaP, DT, Tdap, Td)

If an error occurs, determine how the error occurred and take the appropriate actions to put strategies in place to prevent it from happening in the future. The following table outlines common vaccine administration errors and possible preventive actions you can take to avoid errors.

Error(s)	Possible Preventive Actions
Wrong vaccine, route, site, or dosage (amount); or improperly prepared.	Circle important information on the packaging to emphasize the difference between the vaccines.
	Include the brand name with the vaccine abbreviation whenever possible (e.g., PCV13 [Prevnar13]) in orders, medical screens, etc.
	Separate vaccines into bins or other containers according to type and formulation. Use color-coded identification labels on vaccine storage containers.
	Store look-alike vaccines in different areas of the storage unit (e.g., pediatric and adult formulations of the same vaccine on different shelves in the unit).
	Do not list vaccines with look-alike names sequentially on computer screens, order forms, or medical records, if possible.
	Consider using "name alert" or "look-alike" stickers on packaging and areas where these vaccines are stored.
	Consider purchasing products with look-alike packaging from different manufacturers, if possible.
	Establish "Do NOT Disturb" or no-interruption areas or times when vaccines are being prepared or administered.
	Prepare vaccine for one patient at a time. Once prepared, label the syringe with vaccine name.
	Do not administer vaccines prepared by someone else.
	Triple-check work before administering a vaccine and ask another staff member to check.
	Keep reference materials on recommended sites, routes, and needle lengths for each vaccine used in your facility in the medication preparation area.
	Clearly identify diluents if the manufacturer's label could mislead staff into believing the diluent is the vaccine itself.
	Integrate vaccine administration training into orientation and other appropriate education requirements.
	Provide education when new products are added to inventory or recommendations are updated.
	Use standing orders, if appropriate.

1. National Coordinating Council for Medication Error Reporting and Prevention, https://www.nccmerp.org/about-medication-errors

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Vaccine Administration: Preventing Vaccine Administration Errors

Error(s)	Possible Preventive Actions
Wrong patient	Verify the patient's identity before administering vaccines.
	Educate staff on the importance of avoiding unnecessary distractions or interruptions when staff is administering vaccine.
	Prepare and administer vaccines to one patient at a time. If more than one patient needs vaccines during the same clinical encounter (e.g., parent with two children), assign different providers to each patient, if possible. Alternatively, bring only one patient's vaccines into the treatment area at a time, labeled with vaccine and patient name.
Documentation errors	Do not use error-prone abbreviations to document vaccine administration (e.g., use intranasal route [NAS] to document the intranasal route—not IN, which is easily confused with IM).
	Use ACIP vaccine abbreviations.
	Change the appearance of look-alike names or generic abbreviations on computer screens, if possible.
Improperly stored and/or handled vaccine administered (e.g., expired vaccine given)	Integrate vaccine storage and handling training based on manufacturer guidance and/or requirements.
	Rotate vaccines so those with the earliest expiration dates are in the front of the storage unit. Use these first.
	Remove expired vaccines/diluents from storage units and areas where viable vaccines are stored.
	Isolate vaccines exposed to improper temperatures and contact the state or local immunization program and/or the vaccine manufacturer.
Scheduling errors (e.g., vaccine doses in a series administered too soon)	Use standing orders, if appropriate.
	Create procedures to obtain a complete vaccination history using the immunization information system (IIS), previous medical records, and personal vaccination records.
	Integrate vaccine administration training, including timing and spacing of vaccines, into orientation and other appropriate education requirements.
	For children, especially infants, schedule immunization visits after the birthday.
	Post current immunization schedules for children and adults that staff can quickly reference in clinical areas where vaccinations may be prescribed and administered.
	Post reference sheets for timing and spacing in your medication preparation area. CDC has vaccine catch-up guidance for DTaP, Tdap, Hib, PCV13, and polio vaccines to assist health care personnel in interpreting the catch-up schedule for children.
	Counsel parents and patients on how important it is for them to maintain immunization records.

Adapted with appreciation from Table 11-2, Medication Errors, 2nd ed, by Cohen, Michael. Washington D.C: American Pharmacists Association; 2007.

Healthcare providers are strongly encouraged to report vaccine administration errors to Vaccine Adverse Event Reporting System (VAERS).* To file an electronic report, please see the VAERS website at https://vaers.hhs.gov/reportevent.html

* At this time, COVID-19 vaccination has additional VAERS reporting requirements, including required reporting of vaccine administration errors. Please see https://vaers.hhs.gov/faq.html for more information.

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Appendix D

Vaccine Injury Compensation Program (VICP)

The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims. It was established as part of the National Childhood Vaccine Injury Act of 1986, after lawsuits against vaccine manufacturers and healthcare providers threatened to cause vaccine shortages and reduce vaccination rates. It provides compensation to people found to be injured by certain vaccines.

The VICP is administered jointly by the U.S. Department of Health and Human Services (HHS), the U.S. Court of Federal Claims (the Court), and the U.S. Department of Justice (DOJ). The VICP is located in the HHS, Health Resources and Services Administration (HRSA), Healthcare Systems Bureau, Division of Vaccine Injury Compensation.

Who can file a petition?

According to the Health Resources and Services Administration of HHS, a person may file a petition if they:

- received a vaccine covered by the VICP and believe that they have been injured by this vaccine
- are a parent or legal guardian of a child or disabled adult who received a covered vaccine and who they believe was injured by this vaccine
- are the legal representative of the estate of a deceased person who received a covered vaccine and who they believe was injured by the vaccine and/or whose death they believe resulted from the vaccine injury

You may file a petition regardless of age and United States citizenship. The covered vaccine must have been given in the United States or its territories with few exceptions. To learn more about exceptions, see the VICP website (https://www.hrsa.gov/vaccine-compensation/eligible/index.html).

In addition, to be eligible to file a claim, the effects of the person's injury must have:

1. lasted for more than 6 months after the vaccine was given; or
2. resulted in a hospital stay **and** surgery; or
3. resulted in death.

What vaccines are covered?

The **Vaccine Injury Table** makes it easier for some people to get compensation. The Table lists and explains injuries and conditions that are presumed to be caused by vaccines. It also lists time periods in which the first symptom of these injuries and conditions must occur after receiving the vaccine. If the first symptom of these injuries/conditions occurs within the listed time periods, it is presumed that the vaccine was the cause of the injury or condition unless another cause is found. For example, if a patient received the tetanus vaccine and had a severe allergic reaction (anaphylaxis) within 4 hours after receiving the vaccine, then it is presumed that the tetanus vaccine caused the injury, if no other cause is found.

If an injury or condition is not on the Table or if it did not occur within the time period on the Table, the petitioner must prove that the vaccine caused the injury or condition.

A copy of the Vaccine Injury Table is on the following page or can be found online at https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf. A comprehensive explanation of terms used in the table accompanies the online version.

How can a petition be filed?

To learn how to file a petition, see the VICP website at https://www.hrsa.gov/vaccine-compensation/how-to-file/index.html

For more information, visit the VICP website at https://www.hrsa.gov/vaccine-compensation/index.html

National Childhood Vaccine Injury Act: Vaccine Injury Table

This table, supplemented with definitions and other explanatory material, can be found on the National Vaccine Injury Compensation Program's website at https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis	≤4 hours
	B. Brachial Neuritis	2-28 days (not less than 2 days and not more than 28 days)
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (*e.g.,* DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis	≤4 hours
	B. Encephalopathy or encephalitis	≤72 hours
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour
III. Vaccines containing measles, mumps, and rubella virus or any of its components (*e.g.,* MMR, MM, MMRV)	A. Anaphylaxis	≤4 hours
	B. Encephalopathy or encephalitis	5-15 days (not less than 5 days and not more than 15 days)
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours
	D. Vasovagal syncope	≤1 hour
IV. Vaccines containing rubella virus (*e.g.,* MMR, MMRV)	A. Chronic arthritis	7-42 days (not less than 7 days and not more than 42 days)
V. Vaccines containing measles virus (*e.g.,* MMR, MM, MMRV)	A. Thrombocytopenic purpura	7-30 days (not less than 7 days and not more than 30 days)
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient: • Vaccine-strain virus identified	Not applicable
	Vaccine-Strain Measles Viral Infection in an immunodeficient recipient: • If strain determination is not done or if laboratory testing is inconclusive	≤12 months

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio • in a non-immunodeficient recipient	≤30 days
	Paralytic Polio • in an immunodeficient recipient	≤6 months
	Paralytic Polio • in a vaccine associated community case	Not applicable
	B. Vaccine-Strain Polio Viral Infection • in a non-immunodeficient recipient	≤30 days
	Vaccine-Strain Polio Viral Infection • in an immunodeficient recipient	≤6 months
	Vaccine-Strain Polio Viral Infection • in a vaccine associated community case	Not applicable
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
VIII. Hepatitis B vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
IX. *Haemophilus influenzae* type b (Hib) vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1 hour
X. Varicella vaccines	A. Anaphylaxis	≤4 hours
	B. Disseminated varicella vaccine-strain viral disease: • Vaccine-strain virus identified	Not applicable
	Disseminated varicella vaccine-strain viral disease: • If strain determination is not done or if laboratory testing is inconclusive	7-42 days (not less than 7 days and not more than 42 days)
	C. Varicella vaccine-strain viral reactivation	Not applicable
	D. Shoulder Injury Related to Vaccine Administration	≤48 hours
	E. Vasovagal syncope	≤1 hour
XI. Rotavirus vaccine	A. Intussusception	1-21 days (not less than 1 day and not more than 21 days)
XII. Pneumococcal conjugate vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1 hour
XIII. Hepatitis A vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1 hour

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
XIV. Seasonal influenza vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	<48 hours
	C. Vasovagal syncope	≤1 hour
	D. Guillain-Barré Syndrome	3-42 days (not less than 3 days and not more than 42 days)
XV. Meningococcal vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
XVI. Human papillomavirus (HPV) vaccines	A. Anaphylaxis	≤4 hours
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours
	C. Vasovagal syncope	≤1 hour
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage	A. Shoulder Injury Related to Vaccine Administration	≤48 hours
	B. Vasovagal syncope	≤1 hour

(Applies Only to Petitions for Compensation Filed under the National Vaccine Injury Compensation Program on or after March 21, 2017)

Last revised January 2021

Appendix D

Countermeasures Injury Compensation Program (CICP)

The Countermeasures Injury Compensation Program (CICP) is a Federal program that provides benefits for serious injuries that occur as a result of the administration or use of a covered countermeasure. Countermeasures are vaccines, antivirals, drugs, biologics, or medical devices used to diagnose, prevent, or treat, a declared pandemic, epidemic, or security threat. The Secretary of the United States Department of Health and Human Services (the Secretary) declares specific countermeasures under CICP.

This Program was established by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act), 42 U.S.C. § 247d-6e. The PREP Act also confers broad liability protections covering the manufacture, testing, development, distribution, or use of the designated covered countermeasure.

Some examples of covered public health threats are:

- COVID-19
- Ebola
- Pandemic Influenza A
- Smallpox
- Anthrax.

Who is eligible?

The following may be eligible:

- The injured countermeasure recipient
- Certain survivor(s) of a deceased injured countermeasure recipient
- The estate of a deceased injured countermeasure recipient

How can a claim be filed?

Individuals have one year from the date the vaccine or other covered countermeasure was administered or used to request compensation benefits. If their injury is added to a Countermeasures Injury Table, then they may also have one year from the effective date of the Table addition to file. To file a claim, individuals must submit a Request for Benefits Form and the Authorization for Use or Disclosure of Health Information Form to request medical records from each health care provider who treated the injured person. In addition, medical records from one year before the injury to the present time must be submitted.

For more detailed instructions, visit the CICP website at https://www.hrsa.gov/cicp/filing-benefits.

Eligible individuals may be compensated for certain reasonable and necessary medical expenses and for lost employment income at the time of the injury. Death benefits may be paid to certain survivors of covered countermeasures recipients who have died as a direct result of the covered countermeasure injury. The U.S. Department of Health and Human Services is the payer of last resort. Therefore, payments are reduced by those of other third-party payers.

Contact Information

Website: http://www.hrsa.gov/cicp/

E-mail: CICP@hrsa.gov

Phone: 1-855-266-CICP (2427)

Updated January 2021

Additional Resources for Vaccine Safety

Below is a list of additional resources for Vaccine Information Statements (VISs) as recommended.

General Vaccine Safety

- Vaccine Safety: https://www.cdc.gov/vaccinesafety/index.html
- Vaccine Safety Information for Healthcare Providers: https://www.cdc.gov/vaccinesafety/hcproviders/index.html

Safety Monitoring Systems

- Vaccine Adverse Event Reporting System (VAERS): https://vaers.hhs.gov/index.html
- Vaccine Safety Datalink (VSD): https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html

Clinical Immunization Safety Assessment (CISA) Project:

- https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

Compensation Programs

- Countermeasures Injury Compensation Program (CICP): https://www.hrsa.gov/cicp
- National Vaccine Injury Compensation Program (VICP): https://www.hrsa.gov/vaccine-compensation/index.html

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